

REMARKS

This is responsive to the Office Action mailed on August 24, 2007. In the Office Action, claims 1-19, 22, and 40-56 were rejected. The present application currently includes claims 1-15, 17-19, 22 and 40-57. Applicants have amended claims 1, 40, and 49, cancelled claim 16 and added claim 57. Support for the amended claim language is found at least on page 8, lines 6-8, and page 16, lines 19-23. No new matter has been added. Reconsideration and allowance of the claims are requested.

The Office Action rejected claims 1-19, 22 and 40-56 under 35 U.S.C. § 103(a) as being unpatentable over MacGregor (U.S. Pat. No. 4,936,317) in view of Carlyle et al. (International Pub. No. WO 01/41825). The Office Action alleges that the MacGregor patent discloses a heart valve including a rigid carbonaceous solid occluder with a porous surface. The Office Action states that the MacGregor patent does not disclose a filler consisting of mixtures of hydrogel, structural protein and bioactive agents. The Office Action alleges that the Carlyle patent application discloses a coating for heart valve occluders consisting of mixtures of hydrogel, structural protein and bioactive agents for the purpose of causing cell adhesion to the surface. The Office Action alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the occluder of the MacGregor Patent with the coating material of the Carlyle et al. patent application (thereby filling the pores of the occluder) to promote cell adhesion to the surface.

Applicants respectfully disagree that independent claims 1, 40 and 49, as amended, are made obvious by the combination of the MacGregor patent and the Carlyle patent application. An element of each of the independent claims includes a filler comprising a hydrogel or a structural protein or bioactive agents or a mixture thereof, the filler being located within the pores to provide a smoother surface for fluid flow in independent claim 1, to promote cellular attachment and proliferation in claim 40, and where the porous network does not provide significant blood flow through the porous material in claim 49. In each independent claim, the filler also is claimed to prevent back flow of the fluid through the pores of the occluder.

The scope and content of the prior art do not make any of the independent claims obvious. The MacGregor patent teaches away from the use of a filler within the porous structure and the Carlyle patent application does not teach utilizing a hydrogel, structural protein, or bioactive agent within the pores of an occluder.

The MacGregor Patent discloses as follows:

The provision of the porous surface and subsurface network promotes the formation of a smooth, thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the bloodstream.

Col. 1, lines 57-62.

The porous surface intended to engage blood **must have** an interconnected network of pores beneath the surface in fluid flow communication with the surface pores to promote the colonization by nucleated cells and subsequent differentiation into other cell types so that the tissue which is formed and grows into the surface is interlocked into the subsurface network rendering the surface non-thrombogenic. The network of pores preferably extends substantially throughout the body of the pore system.

Col. 2, line 61-Col. 3, line 2 (emphasis added).

Therefore, the MacGregor patent teaches having a porous material where blood flow or other fluid flows through the interconnected network of pores beneath the surface and where the fluid flow is in communication with the surface pores. In Applicants' claims, a filler fills the pores and prevents flow therethrough and specifically prevents back flow through the occluder. This is clearly opposite of the function of the pores as disclosed in the MacGregor patent. Therefore, the MacGregor patent teaches away from utilizing a filler in the pores of the prosthesis.

The Office Action also erroneously alleges that the Carlyle patent application discloses a coating for a heart valve occluder consisting of mixtures of hydrogel, structural protein and bioactive agents for the purpose of causing cell adhesion to the surface. The Carlyle patent application discloses the use of synthetic materials, such as hydrogel, as a component of a prosthesis. (Page 11, lines 19-21). This is the only reference to hydrogel in the Carlyle patent

application.

The Carlyle patent application relates to a medical article having at least a portion of the surface of the article associated with a cell adhesion stimulating protein, such as VEGF, to colonize the ceramic or carbon material. See page 5, lines 10-14 of the Carlyle patent application. There is no disclosure of a substrate having pores in the Carlyle patent application, as pores are not disclosed in the Carlyle patent application. Since no pores are disclosed, there is no disclosure of filling any pores of a substrate in the Carlyle patent application. Further, there is no disclosure of using a hydrogel, structural protein, or a bioactive agent to fill pores in the Carlyle patent application since, again, there is no disclosure of a substrate having pores in the Carlyle patent application.

Claims 1, 40 or 49 are not made obvious by the combination of the MacGregor patent with the Carlyle patent application because the MacGregor patent teaches away from the filling of the pores of the surface and the Carlyle patent application is silent as to a substrate having pores. The rejection was based upon hindsight reconstruction, which is improper. Therefore, reconsideration and allowance of claims 1, 40 and 49 are respectfully requested.

The Office Action also rejected claims 2-19, 22, 41-48 and 50-56 as being obvious over the combination of the MacGregor patent and the Carlyle patent application. While Applicants do not acquiesce to the rejections of the dependent claims, the rejections are moot in light of the fact that independent claims 1, 40, and 49 are in allowable form. Reconsideration and allowance of claims 2-15, 17-19, 22, 41-48, and 50-56 are respectfully requested.

In the Response to Arguments section, the Office Action is alleging that Applicants are attacking the references individually and cites *In Re Keller*. However, Applicants submit that the Office Action is improperly using the claimed invention to make the combination of references. In particular, the MacGregor references teaches away from utilization of a filler as a filler would produce the opposite result of what is disclosed in the MacGregor patent, namely, the promotion of blood flow through the interconnected network of pores to facilitate colonization of cells onto the substrate. Absent the claimed invention, there would be no suggestion in the MacGregor

patent of utilizing a filler, as the filler would prevent blood flow through the pores. Also contrary to the allegations contained in the Office Action, the hydrogel disclosed in the Carlyle Application is a component of the prosthesis, and not a component of the VEGF or other coating. *See* page 11, lines 15-28. Therefore, Applicants submit that the Office Action has misconstrued the Carlyle Application and also has ignored Applicants' arguments that the MacGregor patent teaches away from the utilization of the filler within the pores.

The application appears to be in condition for allowance and favorable action on claims 1-15, 17-19, 22, and 40-57 is requested. If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane, at 612-334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,
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